## **REMARKS**

Reconsideration and allowance are respectively requested in view of the foregoing amendments and the following remarks.

Claims 1-33 are pending in this application.

Claims 1 and 18 have been amended.

Applicant appreciates the telephonic interview with Examiner Deak with respect to independent claims 1 and 18.

## Regarding the § 103 Rejection

Claims 1-4, 6, 14-16, 18-22 and 27-32 were rejected under 35 USC § 103(a) for being rendered obvious by Bonomini (U.S. Patent No. 4,269,708).

Applicant respectfully points out that Bonomini does not teach, allude to, or render obvious a continuous renal replacement therapy device wherein entire device is worn by the patient. Instead, Bonomini teaches and renders obvious a <u>partially</u> wearable dialysis module along with a portable, not wearable, portion having a 20-liter dialysis solution supply tank (col. 6, lines 10-15) and a replaceable filter cartridge. (Figure 2) The 20-liter Bonomini dialysis solution tank is too heavy for a patient to wear and is part of the separate, portable portion of the Bonomini device. Thus, Bonomini teaches a two portion device wherein part of the device is wearable and the other part of the device is both separate and portable. When the wearable portion of the Bonomini device is worn, Bonomini states that both dialysis and ultrafiltration cannot be performed at the same time. Forthermore, Bonomini does not teach, allude to, or render obvious using a plurality of different dialysis sorbents to regenerate the dialysate on a device that is entirely wearable by a patient. Bonomini is limited to teaching the use of a single cartridge 31 that is charged with a single sorbent material, mainly activated carbon (col. 5, lines

32-43). Bonomini does not teach, allude to or render obvious the use of the plurality of different dialysate sorbent devices for regenerating dialysate.

Applicant also respectfully points out that Bonomini teaches away from performing both dialysis and ultrafiltration at the same time. Applicant points out that Bonomini's ultrafiltration is performed in its own phase and Bononimi's dialysis is performed in a separate phase (col. 6, lines 24-28). In the ultrafiltration phase, "blood is drawn [by] the pump 13, where as the reduced pressure is established in the dialyzer, on a dialysis liquid side, by means of pump 17, connected by shunt line 27 and line 29, to the outlet of dialyzer 10, while the output side of pump 17 is connected, via lines 18 and 22, to collection bag 21." (col. 6, lines 29-36) Bonomini goes on to teach specifically that valves 26 and 28 must be suitably controlled to provide the ultrafiltration fluid circuit. (col. 6, lines 36 - 37). During the Bonomini dialysis phase, ultrafiltration is not performed, instead only dialysis is performed when "valve 20 is switched to connect the output side of pump 17, via lines 19 and 23, to the inlet of the dialyzer, while valves 26 and 28 are switched to exclude shunt line 27, the circuit of the dialysis liquid then comprising filter cartridge 31, tank 24 and temperature control device 33." (col. 6, lines 40-46) The dialysis phase then takes place for a period of time at the end of which the portable unit is disconnected from the patient's blood vessels and is ready for the next operation (presumably for the next patient). (col. 6, lines 39-50) Again, Bonomini teaches away from performing ultrafiltration at the same time dialysis is performed. Bonomini clearly indicates that ultrafiltration is not performed while the dialysis phase is being performed. In particular, Bonomini states that the apparatus of the Bonomini invention, due to the complete separation of the ultrafiltration and the dialysis phases, permits not only standard hemodialysis to be performed, but also ultrafiltration alone and dialysis alone by merely suitably adjusting the circuit for the dialysis liquid. (col. 7, lines 33-40) As such, Applicant respectfully points out that Bonomini does not teach, allude to

or render obvious "a microprocessor adapted to control the rate of ultrafiltration at the same time said at least one dialyzer is removing impurities from the blood" in an entirely wearable continuous renal replacement device. Applicant would agree that, Bonomini teaches, and is limited to teaching, the electronic control of valves that enable the fluid circuit for the Bonomini ultrafiltration phase or the Bonomini dialysis phase (col. 6, lines 24-30). But, there is no suggestion in Bonomini to electronically control anything but a valve in a separate, portable, not completely wearable, ultrafiltration or dialysis device. Applicant submits that the Bonomini valves are used to switch operation of the device between the ultrafiltration phase and the dialysis phase and are not taught or suggested to perform any other function.

With respect to independent claim 1, as amended, this claim recites, among other things, "a microprocessor configured to control a rate of ultrafiltration at the same time said at least one dialyzer is removing impurities from the blood." Also, claim 1 has been amended to recite, among other things, that "the entire continuous renal replacement device being worn on the patient." As discussed above, Bonomini does not teach, allude to render obvious a continuous renal replacement therapy device comprising the elements of amended claim 1 including, the ability to control a rate of ultrafiltration at the same time at least one dialyzer is removing impurities from the blood and having the entire continuous renal replacement device being worn by the patient. As such, Applicant respectfully requests that the § 103 rejection be withdrawn and submits that claim is ready for allowance.

Claims 2-4, 6, and 14-16 are either directly or indirectly dependent upon claim 1 and are therefore not rendered obvious for, at least, the same reasons as discussed above with respect to claim 1. Applicant respectfully requests that the § 103 rejection be withdrawn and submits that these claims are ready for allowance.

Independent claim 18, as amended, recites, among other things, that "the entire continuous renal replacement device [is] to be worn on the patient." Again, Applicant respectfully submits that Bonomini does not teach, allude to or render obvious a device comprising the recited elements of claim 18 that can be entirely worn by a patient. Applicant respectfully requests that the § 103 rejection be withdrawn and submits that claim 18 is ready for allowance.

Applicant further notes that Bonomini does not teach, allude to or render obvious a microprocessor that is programmed to control the rate that excess fluid is removed from dialysate while said at least one dialyzer is removing impurities from the blood. As discussed above with respect to Bonomini, Bonomini teaches away from allowing ultrafiltration while removing impurities from the blood. Again, Applicant respectfully submits that claim 18 does not teach, allude to or is rendered obvious by Bonomini and respectfully requests that the § 103 rejection be withdrawn.

Claims 19-22 and 27-32 are each either directly or indirectly dependent upon claim 18 and are therefore not rendered obvious for at least the same reasons as discussed above with respect to claim 18. Applicant respectfully requests that the § 103 rejection be withdrawn and submits that these claims are ready for allowance.

With respect to claims 8, 20 and 23, these claims are either directly or indirectly dependent upon independent claims 1 and 18, respectfully. Applicant further points out that neither Henne nor Greenwood aid in overcoming the deficiencies of Bonomini. Applicant respectfully requests that the remaining § 103 rejections be withdrawn and submits that the remaining claims are ready for allowance.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated:

Respectfully submitted

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